PRICE INQUIRY No NETLA/9/PR34372/2023

In connection with the implementation of the project entitled *"Design and development of an innovative solution - a combination two-component medicinal product in the form of eye drops in multi-dose packaging without preservatives, targeting the treatment of open-angle glaucoma"*, funded by the state budget from the Medical Research Agency, WZF Polfa S.A., **is conducting proceedings for the purchase of a service related to the synthesis and characterization of selected salts of the aminoisoquinoline derivative, testing their stability in accordance with the requirements of ICH Q1A, and the supply of selected salts.**

Below are the questions received by the Contracting Authority on 02.11.2023 and the answers provided:

QUESTION 1.
In section 5.1.4, do you require the preparation of Part S for IMPD?
ANSWER :
Yes, the Bidder is obliged to prepare Part S in the IMPD documentation.

QUESTION 2.
For the manufacturing of the target salt, will the Ordering Party provide the necessary amount of API to the manufacturing site in GMP standard?

ANSWER:
No, the purchase of the raw materials necessary to manufacture the target salt under GMP conditions must be carried out by the Bidder.

QUESTION 3.
Our company does not have a manufacturing site, but we carry out analogous projects in cooperation with proven subcontractors; kindly confirm whether you accept this way of providing the service?

ANSWER:
No, we do not accept the possibility of cooperation with subcontractors to produce the target salt under GMP conditions.